

## **Remarks/Arguments**

New claim 18 has been drafted in order to combine the characteristics of previous claims 10 and 11 as well as to more clearly define the plastic materials from which the multi-layer bag of the present invention may be constructed. The markush group indicated in new claim 18 is cited at page 3 line 26 to page 4 line 10 of the present specification.

Thus, it is further specified that the multi-layer flexible impervious bag of the present invention may be constructed from a variety of plastic materials including polyvinylchloride-based materials, but with the important proviso that any portion of the bag in direct contact with the pharmaceutical preparation of liquid oxaliplatinum does not contain polyvinylchloride-based plastic material.

New claims 19-23 have simply been renumbered and reordered in a more logical form.

New claim 24 defines a plastic material for the bag of the present invention which corresponds to a preferred embodiment, as disclosed in the specification on page 4, lines 20-21.

**Claims 10, 13, 14 and 17 are rejected under 35 USC 102(b) as being anticipated by US 5,716,988.**

This rejection is respectfully traversed.

New claim 18 is indeed novel over US '988 because it now recites the material of the flexible pouch.

As to the Examiner's statement regarding "102(e)," applicant is puzzled and believes this statement was inadvertent.

It is thus respectfully requested that the above cited rejection be withdrawn.

**Claims 11 and 12 are rejected under 35 USC 103(a) as being unpatentable over US '988 in view of US 5,492,534.**

This rejection is respectfully traversed.

It is respectfully submitted that the combination of US '988 with US '534 would neither teach nor suggest the flexible impervious bag as defined in new claim 18.

In particular, neither US '988 nor US '534 describes the specific fact that oxaliplatin is unstable in the presence of polyvinylchloride-based plastic material. It is this central discovery that has permitted the Applicant of the present invention to design the specific flexible impervious bag as indicated in claim 18.

US '988 is entirely silent about any interaction between the oxaliplatin and the bag materials. US '534 simply indicates that polypropylene is an inert material but nowhere indicates that specific interactions may occur between oxaliplatin and polyvinylchloride-based material.

It is thus respectfully requested that the above cited rejection be withdrawn.

**Claims 11, 12 and 16 are rejected under 35 USC 103(a) as being unpatentable over US '988 in view of US 6,007,529.**

This rejection is respectfully traversed.

As with the previous rejection, the combination of US '988 and US '529 does not teach or suggest the specific flexible impervious bag of the present invention.

As already indicated above, US '988 makes absolutely no mention of the unfavorable interaction between oxaliplatin and polyvinylchloride-based plastic materials.

US '529, while indicating that an inner container contained in an outer envelope for storage of parenterally administrable agents may be made of polypropylene, does not in any manner make reference to the unfavorable reaction between oxaliplatin and polyvinylchloride-based plastic materials.

Hence, the specific flexible impervious bag described in claim 18 is not at all obvious over the combination of the prior art references.

It is thus respectfully requested that the above cited rejection be withdrawn.

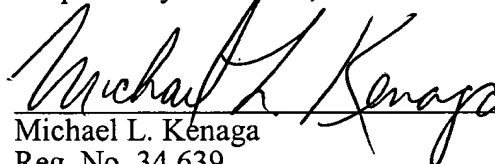
The Applicant notes with appreciation that the Examiner regards previous claim 15 as being allowable if rewritten in independent form including limitations of the base claim and intervening claims.

It is respectfully submitted that new claim 18 reflects this suggestion of the Examiner in so far as the limitations of claims 10 and 11 have been combined and a more restricted definition has been given of the plastic material for constructing the flexible bag.

The Applicant sincerely believes that the scope of claim 18 is fairly based with respect to the Applicant's invention and thus should be allowed.

In view of the above, it is respectfully submitted that the application is now in proper form for allowance.

Respectfully submitted,

  
Michael L. Kenaga  
Reg. No. 34,639

**PIPER RUDNICK**  
P.O. Box 64807  
Chicago, Illinois 60664-0807  
Phone: 312/368-4000

**Customer No.: 28465**